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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,275	01/10/2002	Karl F. Popp	19113-1-0031	8435

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/044,275	POPP, KARL F.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-15,17-26 and 28-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-15,17-26 and 28-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Amendment and Applicants Arguments/Response, both filed 02/10/04 and the Affidavit (Rule 131/132) or Exhibits (5 in total), all filed 11/05/03 is acknowledged.

Claims 1-4, 6-15, 17-26 and 28-45 are pending. Claims 1, 9, 10, 11, 13-15, 28 and 38 have been amended. Claims 5, 16 and 27 have been withdrawn, as requested by Applicant(s). Claims 1-4, 6-15, 17-26 and 28-45 stand rejected.

The 35 U.S.C. §102(b) rejection of claims 1, 12, 13, 15-21, 29 and 38-45 has been *withdrawn* by virtue of the Amendment.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 6-15, 17-26 and 28-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Czernielewski *et al.* (US Pat. No. 5,849,776) in view of Buseman *et al.* (US Pat. No. 6, 495,158 B1).

Czernielewski *et al.* teach dermatological compositions and methods for treating dermatological conditions comprising formulations based on metronidazole or a combination of metronidazole and clindamycin, wherein the composition is intended as an anti-inflammatory treatment suitable for application by the topical route and whereby the composition can be in the form of ointments, creams, milks, powders, *impregnated pads*, solutions, gels, sprays, lotions or suspensions. These compositions can be provided either in anhydrous form or in aqueous form (see reference column 1, line 46 through col. 2, line 48) and Abstract.

The composition, which is preferable for topical use, contains metronidazole at a concentration preferably of between 0.01% and 5% by weight of the total composition. This range meets the applicant's claimed range of from about 0.1% to about 2% (col. 2, lines 42-48).

The composition may also additionally contain inert or even pharmacodynamically or cosmetically active additives or combination of additives, such as wetting agents, de-pigmenting agents, emollients, hydrating agents such as glycerol, anti-acne agents, preserving agents and stabilizing agents, for example (col. 2, lines 53 through col. 3, line 8).

The examples at columns 3-4 demonstrate the topical anti-inflammatory activity of metronidazole and of a metronidazole plus clindamycin combination.

Czernielewski *et al.* also teach a method for the treatment of inflammation, which comprises administering an effective amount of metronidazole and a topical pharmaceutically acceptable carrier. The method of treatment comprises treatment for

various skin diseases accompanied by dermatosis, such as eczema, psoriasis, acne rosacea, acne vulgaris, ulcers, and the like (col. 4, lines 53 through col. 6, line 16).

Czernielewski *et al.* teach topical administration of metronidazole whereby the composition can be in the form of ointments, creams, milks, powders, *impregnated pads*, solutions, gels, sprays, lotions or suspensions.

Czernielewski *et al.* are deficient only in the sense that they do not explicitly teach the particular features of the substrate (woven, non-woven, sponge, etc).

Buseman et al. teach an acne patch which comprises a therapeutic formulation of a topical acne drug, a solvent that dissolves the topical acne drug and a pressure sensitive adhesive whereby the patch can be made of various materials, such as woven, non-woven fabrics, natural fibers such as polyester, cotton fibers, polymeric fibers, porous films, or other kinds of matrixes and can further include antimicrobials, such as metronidazole, clindamycin and the like (see reference column 4, line 21 through col. 10, line 67); (col. 18, lines 1-30).

Therefore it would have been obvious to one of ordinary skill within the art to use the teachings of Buseman et al. within the teachings of Czernielewski et al. because Buseman et al. teach a topical therapeutic acne patch device or substrate wherein the patch is composed of various materials (i.e., woven, non-woven fabrics, natural fibers such as polyester, cotton fibers, etc.), which serve to retain the therapeutic formulation and can further include antimicrobial agents (i.e., metronidazole, clindamycin) and similarly Czernielewski et al. teach dermatological compositions comprising

metronidazole or a combination of metronidazole and clindamycin, wherein the composition is applied by the topical route and can include such forms as ointments, *impregnated pads* and the like. The expected result would be an improved topically administered dermatological formulation for the effective treatment of a variety of skin conditions, including, acne and rosacea.

Regarding the instantly claimed amounts or percentages of the delivery system, it is deemed obvious to one of ordinary skill in the art that suitable percentages could be obtained through the use of routine or manipulative experimentation, as these are all variable parameters.

Response to Arguments

Applicant's arguments filed 02/10/04 have been fully considered.

Firstly, the Applicant argued regarding the 35 §102(b) rejection of claims 1, 12, 13, 15-21, 29 and 38-45 over Czernielewski et al. (US 5,849,776) stating, "the scope of Czernielewski has been restricted to combinations of metronidazole and clindamycin". These arguments have been considered. The Czernielewski et al. reference teaches the concept of the use of metronidazole and the "comprising" claim language permits the use of additional ingredients in the formulation, even active ingredients. Additionally, by virtue of the Amendment filed 02/10/04, the 35 U.S.C. §102(b) rejection has been withdrawn. The Office Action has been reformulated to contain a single 35 U.S.C. §103 (a) rejection over Czernielewski *et al.* in view of Buseman *et al.*

Secondly, the Applicant argued regarding the 35 §103 (a) rejection of claims 2-11, 14, 22-28 and 30-37 over Czernielewski *et al.* (5,849,776) in view of Buseman *et al.* (6,495,158 B1) stating, "Czernielewski *et al.* lacks critical elements which are present in the present invention. These critical elements are also lacking in Buseman *et al.* The Examiner's refusal under 35 U.S.C. §103 (a) cannot be sustained on the basis of Czernielewski *et al.* alone, nor in combination with Buseman et al."

Applicants arguments have been fully considered but are not found persuasive. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Czernielewski *et al.* is relied upon for their teaching of dermatological compositions comprising formulations based on metronidazole (or a combination of metronidazole and clindamycin), wherein the composition is in various forms, of which, impregnated pads are explicitly included. Czernielewski *et al.* is deficient only in the sense that they do not teach particular features of the substrate (woven, non-woven, sponge, etc). Buseman *et al.* is relied upon to resolve this deficiency of Czernielewski *et al.* by teaching a metronidazole patch made of woven, non-woven fabrics, natural fibers such as

polyester, cotton fibers, polymeric fibers, porous films, or other kinds of matrixes. Hence, ample motivation is provided by the prior art.

Next, the Applicant argued, "Buseman et al. is ineffective as a reference under 35 §103 (a) as it describes an adhesive 'patch' and not a 'pledget'".

This argument has been fully considered but was not found persuasive. The primary reference of Czernielewski *et al.* initially teaches the incorporation of active ingredients, particularly, metronidazole in various forms that clearly include "impregnated pads" which are functionally equivalent to non-adhesive impregnated supports. It is not necessary that the secondary reference of Buseman *et al.* also teach an impregnated support or pledgets, as instantly claimed, since the primary reference adequately recognizes the concept of formulating dermatological active ingredients into impregnated pads. Moreover, Buseman *et al.* teach the incorporation of metronidazole into similar forms relating to pledgets and teach a formulation in the same field of endeavor, with the same purpose as the Applicants, delivering a dermatological composition effectively. Hence, Applicant's arguments are not persuasive.

Lastly, the Applicant argued "Applicant's date of invention pre-dates *Buseman's* effective date as a reference."

With regards to the Declaration (Exhibits) filed by the Applicant, the Declaration has been carefully considered, however fails to establish completion of the claimed invention, prior to the date of Buseman *et al.* ('158). There is no information that supports a dermatological delivery system that is non-adhesive and manufactured from the materials claimed and contains about 0.1% to about 2% solution of metronidazole.

The generic concept has not been supported by the Declaration, nor has claims to the additional species limitations. This includes concentrations, supports, % polymer, major solvents and thickness. The evidence fails to establish completion of the invention as claimed prior to 01/19/01 (filing date of Buseman et al.). Hence the instant invention remains obvious and unpatentable over the prior art of record.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns H.N.S.
June 07, 2004

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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